

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 29, 2021

Silverback Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39756
(Commission
File Number)

81-1489190
(IRS Employer
Identification No.)

500 Fairview Ave N, Suite 600
Seattle, Washington
(Address of principal executive offices)

98109
(Zip Code)

Registrant's telephone number, including area code: (206) 456-2900

N/A
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	SBTX	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On March 29, 2021, Silverback Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the three and twelve months ended December 31, 2020. A copy of the press release is attached hereto as Exhibit 99.1.

The information in this Item and the exhibit attached hereto are being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933, as amended, whether filed before or after the date hereof and regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press Release of Silverback Therapeutics, Inc., dated March 29, 2021.</u>

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SILVERBACK THERAPEUTICS, INC.

By: /s/ Laura Shawver, Ph.D.

Laura Shawver, Ph.D.

Chief Executive Officer

Dated: March 29, 2021

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Silverback Therapeutics Reports Fourth Quarter and Full Year 2020 Financial Results and Recent Corporate Updates

Initiated SBT6050 clinical development, with pharmacological activity demonstrated in the first dose cohort

Advanced preclinical development of SBT6290 and declared SBT8230 as the development candidate for chronic hepatitis B virus program

Raised \$441.2 million including \$277.7 million in gross proceeds from our IPO

\$386.6 million in cash and cash equivalents at end of 2020

SEATTLE – March 29, 2021 – Silverback Therapeutics, Inc. (Nasdaq: SBTX) (“Silverback”), a clinical-stage biopharmaceutical company leveraging its proprietary ImmunoTAC technology platform to develop systemically delivered, tissue targeted therapeutics for the treatment of cancer, chronic viral infections, and other serious diseases, today reported financial results and provided a corporate update for the fourth quarter and full year ended December 31, 2020.

“2020 was an extraordinary year for Silverback, with the initiation of our first clinical study for SBT6050, in which pharmacological activity was observed in the first dose cohort, the advancement of each of our preclinical programs, expansion of our strong team, and the successful closing of our IPO in December,” said Laura Shawver, Ph.D., chief executive officer of Silverback. “We are well-positioned to execute on our mission to develop a new class of tissue-localized therapies that are designed to modulate fundamental biological pathways in cancer and beyond.”

2020 Corporate Highlights and 2021 Anticipated Milestones

- ***SBT6050 (HER2-TLR8 ImmunoTAC) Phase 1/1b clinical study initiated, with pharmacological activity demonstrated in the first dose cohort.*** SBT6050 is being studied as a monotherapy and in combination with pembrolizumab, in patients with advanced or metastatic HER2-expressing solid tumors. Changes in pharmacodynamic markers consistent with the potential mechanism of action have been observed in

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patients treated in the first monotherapy dose cohort. Enrollment is ongoing in Part 1 of the study (SBT6050 monotherapy dose escalation) and treatment has been initiated in Part 3 of the study (SBT6050 plus pembrolizumab dose-escalation). Silverback is on track to deliver interim clinical data from Part 1 of the study in the second half of 2021.

- **SBT6290 (Nectin4-TLR8 ImmunoTAC) continues to advance through preclinical development.** SBT6290 includes the same TLR8 agonist linker-payload used in SBT6050, conjugated to a proprietary Nectin4-directed monoclonal antibody. Pre-Investigational New Drug (IND) alignment with the FDA was achieved in February 2021 and an IND application is expected in the fourth quarter of 2021. The initiation of a Phase 1/1b clinical study is anticipated in the first quarter of 2022.
- **SBT8230 (ASGR1-TLR8 ImmunoTAC) development candidate selected in the fourth quarter of 2020.** SBT8230 includes the same TLR8 agonist linker-payload used in SBT6050, conjugated to a proprietary ASGR1-directed monoclonal antibody, and is designed to activate human myeloid cells in the liver for treatment of chronic hepatitis B viral infection. CMC scale up and preclinical work continues with IND-enabling toxicology studies expected to commence in the first quarter of 2022.
- **Completed initial public offering resulting in \$277.7 million in gross proceeds.** Silverback completed an IPO in December 2020, selling 13,225,000 shares at a public offering price of \$21.00 per share, raising gross proceeds of \$277.7 million (before deducting underwriting discounts and commissions and offering costs). In September 2020, the Company completed a Series C financing, raising \$85.0 million in gross proceeds, and in March, July and September 2020, completed a Series B financing, raising \$78.5 million in gross proceeds (including \$10.1 million upon the conversion of then outstanding convertible notes and accrued interest thereon).

Financial Results

For the fourth quarter ended December 31, 2020, Silverback reported a net loss of \$13.1 million, compared to a net loss of \$7.0 million for the comparable period in 2019. For the year ended December 31, 2020, the Company reported a net loss of \$32.9 million, compared to a net loss of \$24.0 million for 2019. Net loss for the fourth quarter and full year of 2020 included non-cash stock-based compensation expense of \$2.3 million and \$2.6 million, respectively, compared to \$42,000 and \$148,000 for the same periods in 2019, respectively.

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Research and development expenses for the fourth quarter ended December 31, 2020 were \$8.8 million, compared to \$6.3 million for the same period in 2019. For the year ended December 31, 2020, research and development expenses were \$24.6 million, compared to \$21.5 million for 2019. The increases in the Company's research and development expenses for the 2020 periods, as compared to the same periods in 2019, were primarily attributable to the advancement of pipeline programs, including SBT6290 and SBT8230, into preclinical development. Silverback also incurred additional personnel-related expenses in 2020 as compared to 2019 as operations grew in support of program advances. These increases were partially offset by a decrease in expenses related to the development of SBT6050 as the program completed manufacturing activities and initiated a Phase 1/1b clinical trial in the second half of 2020.

General and administrative expenses for the fourth quarter ended December 31, 2020 were \$4.3 million, compared to \$0.7 million for the same period in 2019. For the year ended December 31, 2020, general and administrative expenses were \$8.3 million, compared to \$2.6 million for the same period in 2019. The increases in general and administrative expenses for the 2020 periods, as compared to the same periods in 2019, were primarily attributable to an increase in personnel-related expenses due to increased headcount in 2020, including new executives, as well as increases in salaries, bonuses, and stock-based compensation. The increase in general and administrative expenses was also due to an increase in legal fees, professional fees, and other various general and administrative expenses as we prepared to become a public company.

As of December 31, 2020, Silverback reported cash and cash equivalents of \$386.6 million, compared to \$10.0 million at December 31, 2019, which is expected to fund operating expenses and capital expenditure requirements for at least the next 24 months. The Company's cash and cash equivalents balance at December 31, 2020 included \$255.3 million of proceeds, net of offering costs, from the Company's initial public offering in December 2020, and \$153.3 million of proceeds, net of offering costs, from the Company's Series B and Series C financings in 2020. As of December 31, 2020, the Company had 34,801,537 common shares outstanding.

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About Silverback Therapeutics

Silverback Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on leveraging its proprietary ImmunoTAC technology platform to develop systemically delivered and tissue targeted therapeutics for the treatment of cancer, chronic viral infections, and other serious diseases.

Silverback's platform enables the strategic pairing of proprietary payloads that modulate key disease modifying pathways with monoclonal antibodies directed at specific disease sites. Initially, Silverback is creating a new class of targeted immuno-oncology agents that direct a TLR8 agonist myeloid cell activator to the tumor microenvironment in solid tumors to promote cancer cell killing. Silverback Therapeutics is located in Seattle, Washington. To learn more, visit www.silverbacktx.com.

Forward-Looking Statements

This news release contains certain forward-looking statements that involve risks and uncertainties that could cause actual results to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. Such forward-looking statements include statements regarding, among other things, Silverback's plans and ability to bring new treatments to patients in need, the progress and expected timing of Silverback's drug development programs and clinical trials, the strength of Silverback's balance sheet and the adequacy of cash on hand. Factors that may cause actual results to differ materially include the risk that compounds that appeared promising in early research or clinical trials do not demonstrate safety and/or efficacy in later preclinical studies or clinical trials, the risk that Silverback may not obtain approval to market its product candidates, uncertainties associated with performing clinical trials, regulatory filings and applications, risks associated with reliance on third parties to successfully conduct clinical trials, the risks associated with reliance on outside financing to meet capital requirements, and other risks associated with the process of discovering, developing and commercializing drugs that are safe and effective for use as human therapeutics, and in the endeavor of building a business around such drugs. You are urged to consider statements that include the words "may," "will," "would," "could," "should," "believes," "estimates," "projects," "promise," "potential," "expects," "plans," "anticipates," "intends," "continues," "designed," "goal," or the negative of those words or other comparable words to be uncertain and forward-looking. For a further list and description of the risks and uncertainties that Silverback faces, please refer to Silverback's periodic and other filings with

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the Securities and Exchange Commission, which are available at www.sec.gov. Such forward-looking statements are current only as of the date they are made, and Silverback assumes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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Silverback Therapeutics, Inc.
Balance Sheets
(in thousands, except share and per share data)
(unaudited)

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 386,569	\$ 9,976
Prepaid expenses and other current assets	4,087	552
Total current assets	390,656	10,528
Property and equipment, net	1,618	1,316
Restricted cash	350	550
Right-of-use asset	2,180	3,253
Total assets	<u>\$ 394,804</u>	<u>\$ 15,647</u>
Liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 2,583	\$ 3,518
Accrued expenses	5,278	2,112
Term loan payable, net	844	1,522
Convertible notes, net	—	9,991
Current portion of lease liability	896	783
Total current liabilities	9,601	17,926
Lease liability, net of current portion	2,326	3,324
Total liabilities	<u>11,927</u>	<u>21,250</u>
Commitments and contingencies		
Redeemable convertible preferred stock, \$0.0001 par value per share; no shares and 17,142,854 shares authorized, no shares and 15,714,283 shares issued and outstanding with aggregate liquidation preference of \$0 and \$55,000 at December 31, 2020 and 2019, respectively	—	53,174
Stockholders' equity (deficit):		
Preferred Stock, \$0.0001 par value per share; 10,000,000 and no shares authorized at December 31, 2020 and 2019, respectively; no shares issued and outstanding at December 31, 2020 and 2019	—	—
Common stock, \$0.0001 par value per share; 200,000,000 and 23,500,000 shares authorized, 34,801,537 and 670,477 shares issued, and 34,701,274 and 664,431 shares outstanding at December 31, 2020 and 2019, respectively	3	—
Additional paid-in capital	479,608	5,010
Accumulated deficit	(96,734)	(63,787)
Total stockholders' equity (deficit)	<u>382,877</u>	<u>(58,777)</u>
Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)	<u>\$ 394,804</u>	<u>\$ 15,647</u>

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Silverback Therapeutics, Inc.
Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	\$ 8,837	\$ 6,273	\$ 24,577	\$ 21,505
General and administrative	4,264	658	8,341	2,562
Total operating expenses	<u>13,101</u>	<u>6,931</u>	<u>32,918</u>	<u>24,067</u>
Loss from operations	(13,101)	(6,931)	(32,918)	(24,067)
Interest income (expense), net	16	(39)	(29)	100
Net loss and comprehensive loss	<u>\$ (13,085)</u>	<u>\$ (6,970)</u>	<u>\$ (32,947)</u>	<u>\$ (23,967)</u>
Net loss per share applicable to common stockholders, basic and diluted	<u>\$ (1.37)</u>	<u>\$ (10.51)</u>	<u>\$ (11.33)</u>	<u>\$ (36.27)</u>
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	<u>9,563,986</u>	<u>663,406</u>	<u>2,907,542</u>	<u>660,893</u>